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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,138	12/13/2001	Thomas Schultz	ORT-1548	2788
27777	7590	01/23/2008	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			QAZI, SABIHA NAIM	
			ART UNIT	PAPER NUMBER
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			01/23/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/022,138	<b>Applicant(s)</b> SCHULTZ ET AL.	
	<b>Examiner</b> Sabiha Qazi	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 6 and 7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 6 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**Non-Final Office Action**

Claims 1, 6 and 7 are pending. No claim is allowed at this time. Amendments are entered.

**Summary of this Office Action dated December 09, 2007**

1. Continued Examination Under 37 CFR 1.114
2. Information Disclosure Statement
3. Copending Applications
4. Specification
5. 35 USC § 103(a) Rejection
6. Response to Arguments
7. Communication

### **Information Disclosure Statement**

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### **Copending Applications**

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See *Dayco Products Inc. v. Total Containment Inc.*, 66 USPQ2d 1801 (CA FC 2003).

### **Specification**

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

**Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/16/2007 has been entered.

**Claim Rejections - 35 USC § 103 (a)**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6 and 7 are rejected under 35 U.S.C. 103(a) over GAST<sup>1</sup>, in view of MORITA, MERCK<sup>2</sup>; JAIN et al., et al. (European J. of Pharmaceuticals and Biopharmaceutics, 46, (1998), 177, 182); Rialkar et al and Bouckton et al. ((IDS references)). In specification Example 1 on page 15 and Table 7 on page 21 a progestin norgestimate is disclosed.

GAST teaches a hormonal product with an excipient in crystalline and non-crystalline form, which embraces applicant's claimed invention. See the entire documents especially examples 1 and 2, claims, lines 11-19 and lines 31-67 in col. 7 of GAST.

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<sup>1</sup> United States of America Patent No. 5,858,405.

<sup>2</sup> Merck Index, 12<sup>th</sup> edition, page 632 (3751)

MORITA teaches that lactose has been widely used for solid pharmaceutical preparations and many grades are available for example official grade, crystalline, anhydrous, spray dried, or granulated lactose. Anhydrous and spray-dried and granulated lactose preparations have been used in direct compression applications. This classification is based on the manufacturing methods. On the other hand lactose has four crystallographic forms, namely alpha-monohydrate, alpha-anhydrate, beta-anhydrate and amorphous form. See the entire document especially abstract, Tables I-III and page 4076 of the reference.

MERCK in section 3751 teaches that estrone *can be* crystallized.

JAIN teaches the stability of a hydrophobic drug in presence of hydrous and anhydrous lactose. See the entire document especially abstract and introduction.

SEBHATU et al.; RIALKAR et al and BOUCKTON et al. and JAIN et al. teach the use of lactose. See the entire documents.

Instant claims differ from GAST in claiming a broader scope of non-crystalline steroid hormone. The difference between the instant invention and GAST is that the instant invention specifically claims the non-crystalline form while GAST is silent on specifically naming crystallization (Even though GAST discloses "Preferred salts of estrone include but are not limited to the sodium and piperate salt," it does not specifically use the words *crystalline* or *non-crystalline*) and MORITA et al which teaches the use of lactose in pharmaceutical preparations. MERCK in cited section 3751, teaches that estrone *can be* crystallized which means that it was not crystalline before. Also it can be used as estrones or

its salts which can be crystallized or non-crystallized. GAST teaches the use of **lactose** in the formulation see example 1 on page 13 (example 1).

It would have been obvious to one skilled in the art to prepare additional beneficial compositions for hormone replace therapy and other estrogen deficiencies because GAST teaches the limitations of the instantly claimed invention. Since GAST is silent on crystallization and lactose, the Examiner has cited MORITA which teaches use of lactose in pharmaceutical preparations and MERCK, which teaches the crystallization process of estrone to show that estrone exists in both non-crystalline and crystalline forms. JAIN teaches the use stability of hydrophobic drugs in presence of hydrous and anhydrous lactose.

Since no unexpected results and/or criticality seen, it would have been *prima facie* obvious to make and/or use non-crystalline form of the norgestimate teaching of GAST, MORITA, MERCK, *et al.*, RAILKAR *et al.*, BOUCKTON *et al.* and JAIN *et al.* at the time of invention presently claimed invention would have been obvious to one skilled in the art.

The instant invention is *prima facie* obvious over the combined teachings of the prior art cited above.

See KSR Supreme Court of United States Decision (Decided April 30, 2007, KSR INTERNATIONAL CO. v. TELEFLEX INC. et al. No. 04-1350) where it states that (1) "However, the issue is not whether a person skilled in the art had the motivation to combine the electronic control with an adjustable pedal assembly, but whether a person skilled in the art had the motivation to attach the electronic control to the support bracket of pedal assembly". (2) "the results of ordinary innovation are not the subject of exclusive rights under the patent laws". In



the present case the product as claimed would have been obvious to one skilled in the art at the time the invention was made.

In absence of any criticality and/or unexpected results instant invention is considered *prima facie* obvious to one skilled in the art.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

#### **Response to Arguments**

Claims are amended therefore written description rejection is withdrawn. Obviousness rejection is maintained because arguments are not found persuasive for the same reasons as set forth in the previous office action.. Applicant argue that "in the manufacture of steroid hormone products it would be highly desirable to increase the dissolution rate of the hormone while at the same time either improving or at least not reducing the physical/chemical stability of the hormone. These objectives are achieved by the claimed invention, as shown by the data set forth in Tables 1-4. In particular, the data in Table 1 demonstrate the difference in dissolution rates for non-crystalline norgestimate as compared to the lower-energy crystalline form. Note, that the dissolution rate for amorphous norgestimate at 60 minutes is about the same as the lower energy crystalline form at 120 minutes and that the dissolution rate for the amorphous form at 120

minutes is significantly higher than the rate for the crystalline form at 140 minutes. The data in Tables 2 and 3 illustrates the effect on dissolution rate as norgestimate begins to re-crystallize from the higher energy amorphous form. As shown by these data, the dissolution rate of norgestimate decreases as the steroid converts to the lower energy crystalline form. The data in Table 4 show that the dissolution properties of norgestimate are not only dependent on storage conditions, but also on the mixing energetics imparted during the manufacturing process. Note that as energy is imparted over time and higher levels of amorphous norgestimate are present, the dissolution characteristics improve even when storage is unprotected under accelerated conditions.

As stated in the specification at page 13, lines 11-22, taken together the data from these studies demonstrate that when a mixture of an excipient and a steroid active ingredient is subjected to sufficient mechanical energy, the excipient and the steroid active ingredient form a less crystalline, more highly energetic composition. Furthermore, under appropriate mixing conditions, the lactose component stabilizes the steroid in a highly energetic, substantially non-crystalline state, thus preventing recrystallization of the steroid. The highly energetic, non-crystalline steroid active ingredient dissolves more readily and is better able to maintain desirable dissolution characteristics under a variety of conditions of ambient humidity and ambient temperature”.

Since MERCK, which teaches the crystallization process of estrone to show that estrone exists in both non-crystalline and crystalline forms.

In summary Examiner concludes that claims and specification does not provide any new concept or invention for the reasons cited above. To emphasize this point Examiner would like

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to refer to Applicants to Genetech, 108 F.3d at 1366 and Brenner 383 U.S. 519, 536, 148 USPQ 689, 696 (1966)" which states that "a patent is not a hunting license. It is not a reward for research, but a compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague limitations of general ideas that may or may not be workable."

### **Communication**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi, Ph.D. whose telephone number is 571-272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, Ph.D. can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA QAZI, PH.D.  
PRIMARY EXAMINER